

## **REMARKS**

In accordance with the forgoing, claims 1, 4, 13, 14, 21, 24, 33, 41, 44, 49, 55, and 57 have been amended, and claims 16 and 36 have been canceled without prejudice or disclaimer of the subject matter contained therein. Claims 1, 4-15, 17-21, 24 35, 37-41 and 44-57 are pending and under consideration.

### **I. Rejections Under 35 USC § 102**

Claims 1, 4, 13-15, 20-21, 24, 33-35, 39-41, 44, 49-51 and 55-57 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,957,861 to Combs et al. et al. ("Combs"). Applicants respectfully assert that the claims of the present invention are patentably distinguishable from Combs, and the rejection is respectfully traversed.

Combs teaches the determination of the extent and progression of edema based on a single data point (LTA-STA), or utilizes a chart or history of the impedance (LTA-STA) versus time to determine the effectiveness of drug therapy. (see column 9, lines 48-59) In addition, as pointed out by the Examiner, Combs teaches using trend data to chart variation over time between the short term and long term average. (see column 11, lines 32-36).

As described at paragraphs [0093] to [0096], in reference to FIG. 8A for example, the inventors have determined that in instances where measured impedance declines slowly, such changes can be identified by accumulating differences between period average impedances and the baseline impedance during times when there is no crossing of the baseline trend by the short term trend.

Therefore, independent claims 1, 21, 41 and 57 of the present application set forth accumulating, in response to determining no intersecting of the baseline trend by the short term trend, the determined differences between the baseline trend and the calculated period average impedances; and detecting slowly declining changes in impedance in response to the accumulated determined differences.

Combs merely teaches that short term rises, such as would occur if the patient eats a salty meal, are to be detected by changing the rate at which the short and long term measures should be taken. (see column 10, lines 18-25 of Combs). However, merely changing the rate of measurement would not identify slowly declining changes in impedance during instances when there is no crossing of the baseline trend by the short term trend, illustrated in FIG. 8A of the present application. Therefore, Combs does not teach accumulating, in response to determining no intersecting of the baseline trend by the short term trend, the determined differences between the baseline trend and the calculated period average impedances; and detecting slowly declining changes in impedance in response to the accumulated determined differences, as set forth in independent claims 1, 21, 41 and 57 of the present application. Therefore for at least this reason, independent claims 1, 21, 41 and 57 are patentably distinguishable from Combs.

Claims 4, 13-15, 20, 24, 33-35, 39, 40, 44, 49-51, 55 and 56 depend directly or indirectly from independent claims 1, 21 and 41 discussed above, and are submitted as being patentable for the reasons that independent claims 1, 21 and 41 are believed to be patentable, as well as for the reason that these claims further distinguish over the referenced prior art documents. Therefore, for at least the reasons set forth above, claims 1, 4, 13-15, 20-21, 24, 33-35, 39-41, 44, 49-51 and 55-57 are patentably distinguishable from Combs. Accordingly, withdrawal of the rejection is respectfully requested.

## **II. Rejections Under 35 USC § 103**

Claim 52 stands rejected under 35 USC § 103(a) as being obvious over Combs. Applicants respectfully assert that the claims of the present invention are patentably distinguishable from Combs, and the rejection is respectfully traversed.

As set forth above, Combs does not teach or suggest accumulating, in response to determining no intersecting of the baseline trend by the short term

trend, the determined differences between the baseline trend and the calculated period average impedances; and detecting slowly declining changes in impedance in response to the accumulated determined differences, as set forth in independent claim 41 of the present application. Therefore for at least this reason, independent claim 41 and claim 52 dependent thereon are patentably distinguishable from Combs. Accordingly, withdrawal of the rejection of claim 52 is respectfully requested.

Claims 5-12, 17, 18, 25-32 37, 38, 45-48, 53 and 54 stand rejected under 35 USC § 103(a) as being obvious over Combs. Applicants respectfully assert that the claims of the present invention are patentably distinguishable from Combs, and the rejection is respectfully traversed.

As set forth above, Combs does not teach or suggest accumulating, in response to determining no intersecting of the baseline trend by the short term trend, the determined differences between the baseline trend and the calculated period average impedances; and detecting slowly declining changes in impedance in response to the accumulated determined differences, as set forth in independent claims 1, 21 and 41 of the present application. Therefore for at least this reason, independent claim 1 and claims 5-12 dependent thereon, independent claim 21 and claims 25-32 dependent thereon, and independent claim 41 and claims 45-48, 53 and 54 dependent thereon are patentably distinguishable from Combs. Accordingly, withdrawal of the rejection of claims 5-12, 25-32, 45-48, 53 and 54 is respectfully requested.

Independent claim 17 sets forth means for and independent claim 37 sets forth a method that includes updating the adaptive baseline trend by setting the adaptive baseline trend equal to a previous adaptive baseline trend reduced by a predetermined downdrift in response to the current adaptive baseline trend being greater than the current short term trend, and by setting the adaptive baseline trend equal to the previous adaptive baseline trend increased by a predetermined updrift in response to the current adaptive baseline trend being less than the current short term trend, wherein the updrift is greater than the downdrift.

The Examiner asserts that “[i]t would be obvious to modify the trend value of the trend in order to provide predictable results of optimizing the recorded impedance data from the patient.” Applicants respectfully disagree.

In the present disclosure, the baseline trend is intended to approximate the patient’s normal baseline impedance in a healthy state, and thus to facilitate detection of decreases in impedance via accumulations of the difference between the period average impedance and the baseline trend. To approximate the patient’s normal baseline impedance, one could simply apply a smoothing filter to the trend of period average impedances, as is suggested by the Examiner and is well known in the art. However, smoothing filters respond equally to changes in positive and negative directions.

Because the intention of the present disclosure is to detect all decreases in the period average impedance and not to detect increases in the period average impedance, it is critical to design the baseline trend to adapt more rapidly to increases in impedance than to decreases in impedance. In this way, the baseline trend quickly tracks along with increases in the period average impedance, so that any subsequent decrease in the period average impedance can be detected with high sensitivity, because the baseline trend adjusts more slowly to decreases. (see for example, paragraphs [0091] and [0092]). Having the baseline trend adapt more rapidly to increases in impedance than to decreases in impedance by having the updrift being greater than the downdrift is critical since, if adaptation of the baseline trend were equal in positive and negative directions, a loss of sensitivity would result for situations where a transient increase in impedance is followed by a decrease in impedance. The critical feature of detecting decreases in the period average impedance and not to detect increases in the period average impedance is not taught or suggested by Combs, nor is it a mere modification of trend values to achieve more predictable results.

Therefore, Combs does not teach or suggest updating the adaptive baseline trend by setting the adaptive baseline trend equal to a previous adaptive

baseline trend reduced by a predetermined downdrift in response to the current adaptive baseline trend being greater than the current short term trend, and by setting the adaptive baseline trend equal to the previous adaptive baseline trend increased by a predetermined updrift in response to the current adaptive baseline trend being less than the current short term trend, wherein the updrift is greater than the downdrift, as set forth in independent claims 17 and 37. Therefore, independent claim 17 and 37 are patentably distinguishable from Combs.

Claims 18, 19, 38 and 39 depend directly or indirectly from either independent claim 17 or 37 discussed above, and are submitted as being patentable for the reasons that independent claims 17 and 37 are believed to be patentable as well as for the reason that these claims further distinguish over Combs.

Accordingly, for at least the reasons set forth above, withdrawal of the rejection of independent claim 17 and claims 18 and 19 dependent thereon, and independent claim 37 and claims 38 and 39 dependent thereon is respectfully requested

### **III. Conclusion**

Applicant asserts that the remarks presented herein are fully responsive to the Office Action and are sufficient to overcome the rejections presented in the Office Action. However, there may be other arguments to be made as to why the pending claims are patentable. Applicant does not concede any such arguments by having not presented them herein. Applicant respectfully asserts that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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Date

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